

## REMARKS

Claims 1-22 are pending in the application. Claims 7, 11, 12, 14, and 19-22 are withdrawn from consideration. Claims 1-6, 8-10, 13, and 15-18 are rejected. Please reconsider this application in view of the following remarks.

Claims 1-6, and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan, et al. (U.S. Publication 2004/0063663), Inoue et al. (U.S. Patent 5,762,944), and Hughes et al. (U.S. Patent 5,756,659).

Claim 1 recites “introducing a fluid into the mixing apparatus” and “removing at least a volume of the fluid from the mixing apparatus such that an impurity is completely or at least partially removed with the fluid.”

The Examiner states that “Buchanan discloses a method of making a carrier polymer that is used to coat the surface of a stent,” but that “Buchanan does not teach introducing a fluid into the extruder and removing at least a volume of the fluid from the extruder such that an impurity is at least partially removed with the fluid.” The Examiner further indicates that “Inoue teaches a method of a coating for a stent, wherein the coating comprises a polymer” and that “Inoue recognizes the need to wash the polymer to remove impurities.” Furthermore, the Examiner cites Hughes which “teaches a method of removing impurities ... from a molten polymer in a twin-screw extruder” in which “a stripping agent is introduced into the polymer melt stream” ... and “at least some of the stripping agent and impurities are removed from the polymer.”

The Examiner concludes that “it would have been obvious to one of ordinary skill in the art at the time of the invention to have introduced a fluid into the extruder to have removed impurities from the polymer of Buchanan because one skilled in the art would have recognized the need to remove impurities in a method of making a material for a medical device and because Hughes teaches that such an in situ process is suitable in the art of removing impurities from a polymer.” Applicants respectfully disagree.

One of the criteria for a prima facie case of obviousness, as stated in MPEP 2145, is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Thus, to combine the teachings of Hughes et al. and Buchanan et al., i.e., to remove impurities from the polymer of Buchanan using the method of Hughes et al., there must be a suggestion or motivation in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

Apparently to satisfy this requirement, the Examiner cites Inoue et al. which the Examiner indicates demonstrates “the need to remove impurities in a method of making a material for a medical device.” However, Inoue et al. does not provide suggestion of motivation (1) to purify the polymer of Buchanan et al. according to the method of Hughes et al. or (2) to purify the polymer of Buchanan et al. and coat or make an implantable medical device with the purified polymer.

With regard to (1), Inoue et al. teaches “an antithrombotic resin which is prepared by blending at least one type of antithrombotics, in polyurethane or polyurethane urea polymerized by using at least one type of polyether diol.” (Abstract, Inoue et al.) Thus, the polymer of Inoue et al. is a polyurethane or polyurethane urea polymerized by using a polyether diol. Buchanan et al. does not teach or disclose making or using such a polymer. Thus, the Examiner is assuming that need for purifying the polymer of Inoue et al. would also apply to a completely different polymer or polymers disclosed in Buchanan et al.

Such a general conclusion is without support in the cited art. Buchanan et al. does not indicate that impurities or unreacted species are a problem or even mention them. The Examiner appears to be taking official notice without documentary evidence to support a conclusion. According to MPEP 2144, the Examiner must support the finding with adequate evidence.

With regard to (2), Inoue et al. discloses “cleaning” (col. 6, line 41, Inoue et al.) of a polymer used in manufacturing a resin in a “a film form, and when it is used as a medical film such as cataplasma poulticed to cure burns or the like” (col. 3, lines 50-52, of Inoue et al.). Inoue et al. does disclose “coating the surface of a medical apparatus” with the resin, for example, stents. However, the manufacturing method disclosed at col. 6, lines 27-50 of Inoue et al. is directed to forming the thin film above: “liquid is uniformly applied on the outer circumference of a columnar core rod, and is led into a solidifying bath to solidify (form) the resin on the core rod.” (col. 6, lines 32-35, Inoue et al.)

In conjunction with the process for forming the medical film at col. 6, Inoue et al. indicates that “before mixing or dispersing the antithrombotic, by preliminarily sedimenting the polymer by using bad solvent such as methanol, ethanol, acetone, benzene, acetonitrile, water or other dilute solvent, and sufficiently cleaning by Soxhlet extraction or other method, the solvent, unreacted portion or impurity in the polymer may be removed.” (col. 6, lines 38-42, Inoue et al.) Thus, Inoue et al. discloses cleaning a polymer for a medical film that is not implantable. Inoue et al. does not teach or suggest a need for cleaning in association with manufacturing or coating an implantable medical device, such as a stent, with a polymer. Again, the Examiner appears to be assuming facts not supported by the cited art.

The Examiner has not identified a suggestion or motivation for combining Buchanan et al. with Hughes et al. Thus, the Examiner has not demonstrated a *prima facie* case of obviousness. Neither Buchanan et al., Inoue et al., nor Hughes et al. teach all of the elements of claim 1. Thus, claim 1 is patentably allowable over the cited art. Claims 2-6 and 8-10 depend from claim 1 and are allowable for at least the same reason that claim 1 is allowable. Applicants respectfully request removal of the rejection of claims 1-6 and 8-10.

Claims 13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan, et al., Inoue, et al., and Hughes, et al., as applied to claim 1, and further in view of Berg, et al. (European Patent No. 0623354).

Claim 13 recites “introducing a fluid into the extruder,” and “removing at least a portion of the fluid and impurity from the extruder.” As discussed above, Buchanan et al. and Hughes et al. are not combinable. Buchanan et al., Inoue et al., and Hughes et al. on their own do not teach the above mentioned limitations. Berg et al. does not cure the deficiencies of claim 13 with respect to the above-mentioned limitations. Therefore claim 13 is patentably allowable over Buchanan et al., Inoue et al., Hughes et al. and further in view of Berg. et al.

Claims 15-18 depend from claim 13 and are allowable for at least the same reason that claim 13 is allowable. Applicants respectfully request removal of the rejections of claims 13 and 15-18.

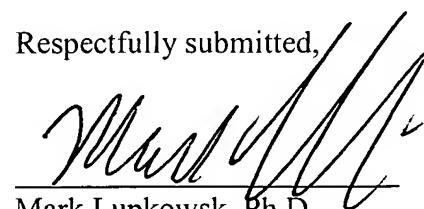
**CONCLUSION**

Examination and allowance of the claims is respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned at (415) 954-0297.

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Respectfully submitted,



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